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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,070	01/29/2007	Andrew R. Gorringe	018872.00167	6579

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HODGSON RUSS LLP
THE GUARANTY BUILDING
140 PEARL STREET
SUITE 100
BUFFALO, NY 14202-4040

EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

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03/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,070	GORRINGE ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-70* is/are pending in the application.

4a) Of the above claim(s) *44-50 and 60-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-59 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *4-7-06* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-7-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed 11-21-08 has been entered into the record.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

The drawings in this application have been accepted. No further action by Applicant is required.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Information Disclosure Statement

The information disclosure statement filed 4-7-06 has been considered. An initialed copy is enclosed.

Election/Restrictions

Applicant's election without traverse of Group **II**, claims 51-59 and new claim in the response filed 11-21-09 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-59 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 51 and all dependent claims, the term "substantially free" in the claims is a relative term which renders the claim indefinite. The term "substantially free" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

As to claim 52, the claim indicates improvement or inhibition and does not provide the basis for comparison and as such, the skilled artisan would not be able to ascertain the metes and bounds of the claim.

Claim Rejections - 35 USC § 102 or 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51-56 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Zollinger et al (US Patent 6,558,677 issued May 6, 2003).

The claims are drawn to methods of treatment or prevention of meningococcal disease by administration of an effective amount of a composition comprising *Neisseria* outer membrane vesicles, wherein said outer membrane vesicles are substantially fee of Opa that binds to CEACAM1.

It is noted that Applicants broadly define the term "opa protein" to encompass analgous proteins from other bacterial species (see page 4, lines 10-13). Applicants also indicated both the meningococcus and gonococcus are obligate human pathogens and, consistent with this, opa variants do not recognize murine or other CEACAM1 (page 12, lines 5-7). As such, opa protein is broadly interpreted as is the genus of CEACAM1. Since

the claims do not specify the specific Opa protein or the specific CEACAM1, the instantly claimed methods are anticipated by the prior art because the composition that is administered is not distinguished from the prior art.

Zollinger et al teach a vaccine for *Neisseria* compsising native outer membrane vesicles (column 5, lines 40-45). Zollinger et al teach immunization of rabbits and mice with the vaccine (column 4). Zollinger et al teach vaccination of humans with the composition (column 5, lines 46-55). Zollinger et al teach native outer membrane vesicles and be prepared from any strain of *Neisseria*, including *N. meningitidis*, *N. gonorrhoeae* and *N. lactima* (paragraph bridging columns 5-6). Zollinger et al teach the native outer membrane vesicles extracted by in sterile saline (see Example 3, column 14) can be combined with stabilizing solutions, filtered to sterilize and the addition of adjuvants, saponin (a surfactant that is also an adjuvant; column 9, lines 4-56). The composition of the prior art administered to mice/rabbits does not bind the homolgous CEACAM1 present in those mammals. Further, the composition of *N. meningitidis* outer membrane vesicles as administered to humans is inherent free of Opa that binds to murine CEACAM1 because as admitted by Applicants the Opa variants of meningococcus and gonococcus do not recognize murine CEACAM1. With respect to claim 70, the claim is drawn to a process limitation of preparing an outer-membrane vesicle preparation and does not distinguish the outer-membrane vesicle product of the prior art that naturally contains Opa proteins precursor or variants that do not bind CEACAM1. As such the claims are anticipated.

Claims 51-59 and 70 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zollinger et al (US Patent 6,558,677 issued May 6, 2003) in view of Foster et al (US Patent 7,384,645, with priority to December 17, 2002).

Zollinger et al teach a vaccine for *Neisseria* compsising native outer membrane vesicles (column 5, lines 40-45). Zollinger et al teach immunization of rabbits and mice with the vaccine (column 4). Zollinger et al teach vaccination of humans with the

composition (column 5, lines 46-55). Zollinger et al teach native outer membrane vesicles and be prepared from any strain of *Neisseria*, including *N. meningitidis*, *N. gonorrhoeae* and *N. lactima* (paragraph bridging columns 5-6). Zollinger et al teach the native outer membrane vesicles extracted by in sterile saline (see Example 3, column 14) can be combined with stabilizing solutions, filtered to sterilize and the addition of adjuvants, saponin (a surfactant that is also an adjuvant; column 9, lines 4-56). The composition of the prior art administered to mice/rabbits does not bind the homolgous CEACAM1 present in those mammals. Further, the composition of *N. meningitidis* outer membrane vesicles as administered to humans is inherent free of Opa that binds to murine CEACAM1 because as admitted by Applicants the Opa variants of meningococcus and gonococcus do not recognize murine CEACAM1. With respect to claim 70, the claim is drawn to a process limitation of preparing an outer-membrane vesicle preparation and does not distinguish the outer-membrane vesicle product of the prior art that naturally contains Opa proteins precursor or variants that do not bind CEACAM1. Zollinger et al differ by not teaching microencapsulation of the native outer membrane vesicles/

Foster et al teach outer membrane vesicles from *Neiseria* species for vaccination. Foster et al teach that the vaccines generally comprise a carrier or if in solution, an aerosol suspension comprising sutiable carriers that can include saline solution, sucrose solution or other pharmaceutically acceptable buffer solutions. Foster et al teach that aerosol formulation typically comprise surfactants. Alternative vaccine compositions include microencapsulated outer membrane vesicle composition that generally comprises a biocompatable polymer shell or core ad made from polylactide-co-glycolide (PLG). Vaccine compositions additional comprise an adjuvant.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time to alternative formulate the native outer membrane Neisseria vaccine according to Zollinger with any of the reagents of Foster et al or as a microencapsulated vaccine according to Foster et al because Foster et al teach that Neisseria outer membrane

vaccines my be alternative formulated as microencapsulated vesicles compositions with a core made from polylactide-co-glycolide.

Status of the Claims

Claims 51-59 and 70 stand rejected. Claims 44-50 and 60-69 are withdrawn from consideration.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner